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| 10/764,235      | 01/23/2004  | Daniel J. O'Mahony   | P26,479-B USA       | 8285             |

23307 7590 07/05/2005

SYNNESTVEDT & LECHNER, LLP  
2600 ARAMARK TOWER  
1101 MARKET STREET  
PHILADELPHIA, PA 191072950

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| EXAMINER |
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ROOKE, AGNES BEATA

|          |              |
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| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/764,235

Applicant(s)

O'MAHONY ET AL.

Examiner

Agnes B Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>none</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's election with traverse of Group I, Claims 1-6, in the reply filed on April 21, 2005 is acknowledged. Also, the Applicant elected SEQ ID NO:24.

The traversal is on the ground that in addition to SEQ ID NO:24, SEQ ID NO:23 also should be examined because it would not be a serious burden to examine an additional sequence.

Examiner respectfully disagrees because SEQ ID NO:23 is distinct from SEQ ID NO:24 because the sequences have different and distinct sequence, and therefore a complete separate search is required to examine SEQ ID NO:23.

The restriction requirement is still deemed proper and is therefore made Final.

Claims 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims.

Claims 1-6 and elected SEQ ID NO:24 are currently under examination. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144).

This application claims priority to 60/156,246, filed on 09/27/1999.

### ***Objection***

In Claims 1 and 2, the name of "MTLP" must be spelled out.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In Claim 1, the Applicant claims all derivatives, fragments, motifs, analogs, or peptidomimetics of SEQ ID NO:2, and thus the written description is not satisfied since all derivatives, fragments, motifs, analogs, or peptidomimetics of SEQ ID NO:2 were not described in the specification.

In Claim 2, the Applicant claims all derivatives, fragments, motifs, analogs, or peptidomimetics of SEQ ID NO:24, and thus the written description is not satisfied since all derivatives, fragments, motifs, analogs, or peptidomimetics of SEQ ID NO:24 were not described in the specification.

In Claims 3-6 the structure or function of an active agent or an active particle is not disclosed in a complex with the MTLp, therefore the claims do not satisfy the written description requirement.

In Claims 1 and 2, Applicant refers to "an amino acid sequence substantially as set forth in SEQ ID NO:2." The substantial SEQ ID NO:2 is not disclosed, and thus the structure of the substantial SEQ ID NO:2 does not correspond with its function.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1 and 2, the word "substantially" is indefinite, because we do not know what is the percent identity to the SEQ ID NO:2, since the term "substantially" is not definite. Also, we do not know what fragments of SEQ ID NO:2 or 24 are claimed, since a fragment of SEQ ID NO:2 or 24 could be an amino acid lysine, for example.

In Claims 1 and 2, the motif of SEQ ID NO:2 or 24 must be provided, such as helix-turn-helix, for example, since proteins contain one or more motifs built from particular combinations of secondary structures.

In Claims 1 and 2, the term peptidomimetic must be more specifically defined, because otherwise the term encompasses any compound that mimics the biological action of the SEQ ID NO:2 or 24.

Claims 3-6 are included in the rejection because they depend from rejected Claims 1 and 2.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al.

(U.S. 6,248,558, filing date Nov. 4, 1998).

Examiner interpreted Claim 1 as comprising a peptide having an amino acid sequence substantially identical as set forth in SEQ ID NO:2. Therefore, the sequence in the prior art must be only substantially identical to SEQ ID NO:2.

According to the U.S. PTO search using GenCore version 5.1.6, in the U.S. 6,248,558, the SEQ ID NO:1 has 79.4% identity to the instant SEQ ID NO:2 claimed in Claim 1, for example. Therefore, the reference would anticipate Claim 1, because 79.4% identity is substantial to 100%.

Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Nadler et al.

(U.S. 5,962,415, filing date May 4, 1998).

Examiner interpreted Claim 24 as comprising a peptide having an amino acid sequence substantially identical as set forth in SEQ ID NO:24. Therefore, the sequence in the prior art must be only substantially identical to SEQ ID NO:24.

According to the U.S. PTO search using GenCore version 5.1.6, in the U.S. 5,962,415, the SEQ ID NO:24 has 70.4% identity to the instant SEQ ID NO:24 claimed

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in Claim 2, for example. Therefore, the reference would anticipate Claim 2, because 70.4% identity is substantial to 100%.

### **Conclusion**

According to the U.S. PTO search engine, examiner did not find amino acid sequence that had 100% identity to the SEQ ID NO:2 or SEQ ID NO:24.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**

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